

Listing of the Claims

Claims 1-75 (canceled)

Claim 76. (previously presented) A method of in-line, continuous production of sterile prefilled syringe bodies for medical purposes, the method comprising the steps of:

- forming a plurality of syringe bodies by injection molding;
- arranging the plurality of syringe bodies in a predetermined order on a transfer mechanism;
- transferring the plurality of syringe bodies along the transfer mechanism to a sterilizing location;
- sterilizing the plurality of syringe bodies by providing a source of electron beam irradiation and irradiating the plurality of syringe bodies with a predetermined dose of the electron beam irradiation;
- transferring the plurality of sterilized syringe bodies into a sterile environment while maintaining the plurality of syringe bodies in a sterilized condition, said sterile environment comprising an enclosed isolator class 100 environment;
- providing a fluid substance within the sterile environment;
- introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment; and
- sealing the fluid substance within the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment.

Claim 77. (original) The method of claim 76 wherein the transfer mechanism includes a conveyor belt.

Claim 78. (original) The method of claim 77 wherein no human intervention is required.

Claim 79. (canceled)

Claim 80. (previously presented) The method of claim 76 wherein the predetermined dose of the electron beam irradiation is between 10kGy and 50 kGy.

Claim 81. (previously presented) The method of claim 80 wherein the predetermined dose of the electron beam irradiation is 25 kGy.

Claim 82. (previously presented) The method of claim 76 wherein the introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment step is performed within six days of the sterilizing the plurality of the syringe bodies step.

Claim 83. (original) The method of claim 82 wherein the fluid substance is a sterile water for injection.

Claim 84. (original) The method of claim 83 wherein the sterile water for injection has a pH of solution between 5.0 and 7.0.

Claim 85. (original) The method of claim 84 further comprising the steps of:
transferring the plurality of syringe bodies from the sterile environment;
storing the plurality of syringe bodies for a predetermined period of time; and
maintaining a pH of solution of the sterile water for injection within a range of 5.0 – 7.0.

Claim 86. (previously presented) The method of claim 76 wherein the introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment step is performed immediately after the sterilizing the plurality of syringe bodies step.

Claim 87. (previously presented) The method of claim 76 wherein the plurality of syringe bodies are formed from a polymeric resin.

Claim 88. (original) The method of claim 87 wherein the polymeric resin is a cyclic olefin copolymer.

Claim 89. (original) The method of claim 88 further comprising the step of weighing and inspecting the plurality of syringe bodies subsequent to forming the syringe body.

Claim 90. (previously presented) The method of claim 76 further comprising the steps of providing a tip cap for each of the plurality of the syringe bodies and fixing the tip cap to an open tip end of each of the plurality of syringe body.

Claim 91. (original) The method of claim 90 further comprising the steps of transferring a plurality of sterilized plungers into the sterile environment and inserting at least one of the plurality of plungers into an open end of each of the plurality of sterile syringe bodies subsequent to the introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment step wherein the fluid substance is sealed within the plurality of syringe bodies.

Claim 92. (original) The method of claim 91 further comprising the step of fixing a plunger rod to each plunger.

Claim 93 (previously presented) The method of claim 76 further comprising the steps of transferring the sterilized plurality of syringe bodies from the sterile environment and resterilizing the plurality of syringe bodies subsequent to filling.

Claim 94 (original) The method of claim 93 further comprising the steps of labeling the plurality of syringe bodies and packaging the plurality of syringe bodies for delivery to an end user.

Claims 95 – 104 (canceled)

Claim 105 (new) A method for producing sterile prefilled syringe bodies comprising:
providing a syringe body;
transferring the syringe body to a sterile environment;
irradiating the syringe body with electron beam radiation during the transferring; and
filling the syringe body with a fluid.

Claim 106 (new) The method of claim 106 further comprising sterilizing the syringe body with electron beam irradiation.

Claim 107 (new) The method of claim 106 wherein the sterilizing occurs at a first location and the sterile environment is at a second location, the method further comprising maintaining the sterility of the sterile syringe body between the first and second locations.

Claim 108 (new) The method of claim 105 wherein the filling further comprises
introducing the fluid into the syringe body while the syringe body is within the sterile environment; and
sealing the fluid within the syringe body while the syringe body is within the sterile environment.